IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 MOTIONS	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' REPLY TO RESPONSE TO MOTION TO EXCLUDE CERTAIN OPINIONS OF DANIEL ELLIOTT, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this reply brief in support of their motion to exclude certain opinions of Daniel Elliott, M.D.

I. The Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI and POP.

Plaintiffs' position that it is appropriate for Dr. Elliott to compare TVT with non-mesh slings cannot be reconciled with Dr. Elliott's admission that "you can't compare TVT mesh, or any mesh for that matter, and the Burch or autologous fascia for that matter." Ex. G to Def's Motion, Elliott 9/26/15 Dep. 74:2-4. No reasonable juror could find that traditional surgical for treating procedures for treating SUI or POP are medical devices, particularly given Dr. Elliott's own admission.

II. Alternatively, the Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI, because his opinions are unreliable.

Dr. Elliott is not competent to testify that TVT Devices are more dangerous than non-synthetic mesh sling procedures, because Dr. Elliott has conceded that he does not even know TVT Device complication rates and he has not cited any reliable studies that support his opinion.

Id. at 110:13-17, 196:7-14. Plaintiffs do not and cannot deny that the crux of Dr. Elliott's opinions is a perceived lack of data. But an expert cannot reliably base opinions on a lack of data. Based on this perceived lack of data, Dr. Elliott wrongly assumes a worst case scenario and relies solely on his personal experiences. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 521 (S.D. W. Va. 2014) (finding that an expert may not assume a worst case scenario).

Dr. Elliott's personal experiences, however, do not afford a reliable basis to provide broad opinions. Just because Dr. Elliott—who may be exceptionally skilled with traditional surgical procedures—has had good results with those procedures does not mean that his success may be broadly translated to others.

The fatal fallacy of Plaintiffs' logic is illustrated in the following hypothetical: Suppose Nike and Titleist are engaged in a lawsuit, and an issue involves which company's golf ball travels farther. The proof shows that the industry driving average (averaging both pro and semi-pro golfers) for Titleist golf balls is 250 yards, which is greater than the Nike average. Nike seeks to present as an expert witness Tiger Woods, who testifies as follows: "I have never hit Titleist golf balls. I don't know how far most golfers drive Nike golf balls, but I know that I drive Nike golf balls an average of 300 yards. Because I personally drive Nike golf balls farther than the Titleist industry average, it is my expert opinion that Nike golf balls travel farther than Titleist golf balls." This would be junk science.

III. The Court should preclude Dr. Elliott from offering design opinions, such as testifying that other synthetic mesh devices offer safer alternatives.

A. Dr. Elliott is not qualified.

Although Dr. Elliott's experience as a urologist may make him qualified to offer certain opinions in this case, there is nothing about his background that makes him competent to testify about product design.

B. Dr. Elliott does not believe that there are safe synthetic mesh alternatives to TVT Devices.

In any event, as Plaintiffs do not dispute that Dr. Elliott is unwilling to stand behind the safety and efficacy of any synthetic mesh alternatives to TVT Devices, the Court should not allow him to suggest that the TVT Devices could have been designed in another way that would have made them safer and equally as effective. It is impossible for Dr. Elliott to testify that a superior product design existed given his unequivocal testimony that *all* mesh products are "unsafe" and that "[m]esh should not be placed in the vagina." Ex. G to Def's Motion, Elliott 9/26/15 Dep. 143:11-14, 144:16-18, 285:22.

C. Lighter Weight/Larger Pore Size Mesh

Dr. Elliott cannot credibility argue that a device with a lighter weight/larger pore mesh would have been more suitable given that, as noted above, he does not believe that any mesh devices are suitable. Notwithstanding Plaintiffs' suggestions, Dr. Elliott could not identify any studies showing that lighter weight mesh is safer than the mesh in TVT and effective for the treatment of SUI. *Id.* at 238:5-241:15. Dr. Elliott could only attempt to extrapolate data from hernia mesh and pelvic organ prolapse devices and apply it to SUI devices, such as TVT. Yet, those devices are different devices with no sheath, different trocar approaches, different placement, and different volume of polypropylene.

As noted by Dr. Marc Toglia, the bulk of studies related to non-SUI mesh devices is "Level 5 data, that you really can't draw any clinical inference or--- or application directly to the TVT device." Ex. A hereto, Toglia 10/2/15 Dep. 324:5-10. Where the Level 5 evidence is incongruent with Level 1 evidence, the lower level evidence is significantly less useful. *Id.* at 327:11-22. Dr. Toglia has explained that research involving hernia mesh is lower-level evidence. *Id.* at 325:14-326:6; Ex. B hereto, Toglia TVT Rep. at 23, 25. For comparison

purposes, it would be difficult to compare a 1.1 cm strip of TVT mesh to large mesh sheets, because the volume difference is so large. *Id.* at 25-26.

In fact, Plaintiffs' position that non-SUI mesh data may be extrapolated is inconsistent with Dr. Elliott's own lament that data concerning lighter weight/larger pore SUI mesh "does not exist and it should exist." Ex. G to Def's Motion, Elliott 9/26/15 Dep. 273:2-275:9. Thus, he concedes that his opinion is hampered by the lack of data.

Plaintiffs cite no study showing that lighter weight, larger pore mesh would be as efficacious at treating SUI. Curiously, Plaintiffs improperly suggest that *Defendants* somehow bear the burden of proving that alternative mesh products are not as efficacious. Doc. 2181, p. 13. Finally, Plaintiffs' brief provides no meaningful response to the fact that Dr. Elliott could not identify any complications that are caused by mesh pore size. Ex. G to Def's Motion, Elliott 9/26/15 Dep. 273:2-275:9.

IV. The Court should preclude Dr. Elliott from criticizing the cut of TVT mesh.

Given Dr. Elliott's admission that "I don't think overall there's going to be a higher risk from one or the other," and that "I am not here today to say that laser cut is better or worse," there is no basis whatsoever for Dr. Elliott to suggest at trial that laser-cut mesh is a safer alternative to mechanically-cut mesh. *Id.* at 226:20-21, 228:16-18. Further, Plaintiffs do not dispute that Dr. Elliott has cited no medical literature that support his opinions about "spiky" edges, roping, curling, fraying, and particle loss.

V. The Court should not allow Dr. Elliott to speculate about the duties of a medical device manufacturer.

A. Research/Testing

Recognizing that this Court has precluded urologists and pelvic surgeons from critiquing testing performed by Ethicon, *see, e.g., Huskey*, 29 F. Supp. 3d at 723, Plaintiffs attempt to

distinguish this Court's rulings by claiming that "Dr. Elliott has no intention to opine on the *legal adequacy* of the testing conducted by Ethicon, but rather on the *factual* underpinnings of whether or not testing was conducted." Doc. 2181, p. 15. Yet, there is nothing about Dr. Elliott's background as a urologist that would substantially assist the trier of fact in determining the simple factual question of whether or not testing was conducted; either it was or it was not. As this Court has appropriately noted, "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct," that are beyond the purview of expert testimony. Ex. K to Def's Motion, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order at 18 (S.D. W. Va. Nov. 20, 2014).

In truth, Plaintiffs hope to misuse Dr. Elliott as part of an attack on Ethicon for purportedly not conducting testing or studies. Dr. Elliott is not competent to opine when a manufacturer should conduct testing or studies or the appropriate levels of such testing/studies. Further, he could only speculate improperly about what any hypothetical testing/studies would have revealed. Consistent with its prior rulings, the Court should disallow such testimony.

B. Adverse Event Reporting

Notwithstanding what is set forth in Dr. Elliott's Prolift report, Plaintiffs have conceded that Dr. Elliott will not "offer opinions or testimony about the FDA regulations or the process of collecting and reporting adverse events to the FDA." Doc. 2181, p. 16.

C. Training

In his Prolift report, Dr. Elliott states that Ethicon "pushed the envelope on training" and criticizes the manner by which Ethicon provided training. Ex. F to Def's Motion, Prolift Report at 43. In their response, Plaintiffs suggest that Dr. Elliott's criticisms of training will be limited to a critique of the adequacy of the IFUs. Doc. 2181, p. 17. To the extent that Dr. Elliott seeks

to criticize training beyond what is set forth in the IFUs, he is not qualified to do so and his opinions are unreliable.

D. Legal Conclusions

Plaintiffs do not dispute that it would be inappropriate for Dr. Elliott to provide legal conclusions.

VI. The Court should preclude Dr. Elliott from testifying about alleged mesh degradation, shrinkage, contraction, and other biomaterials opinions.

A. Degradation

Although the Court in *Bellew*, *supra*, found that Dr. Elliott was qualified to testify about degradation, the Court did not consider any argument by Defendants that Dr. Elliott could not reliably link alleged degradation with any clinical complications. Unlike *Bellew*, that is the issue here. Citing pages 253-254 of Dr. Elliott's September 26, 2015 deposition, Plaintiffs suggest that Dr. Elliott has reliably attributed alleged polypropylene degradation to complications. Doc. 2181, p. 19 (citing Def's Motion Ex. G). Those pages simply do not show that Dr. Elliott has reached such an opinion within any degree of medical certainty. In fact, Dr. Elliott lamented that he could not reach such an opinion due to the absence of studies. Ex. G to Def's motion, Elliott 9/26/15 Dep. 254:7-18.

B. Shrinkage/Contraction

In their response, Plaintiffs appear to acknowledge that Dr. Elliott's opinions about shrinkage and contraction are unsupported by SUI mesh studies. As set forth in Section III.C above, Dr. Elliott's attempt to extrapolate data from non-SUI devices to TVT Devices is wholly unreliable.

C. MSDS Sheet

Plaintiffs do not respond to Defendants' argument that Dr. Elliott is not competent to testify about the PROLENE MSDS sheet, and therefore, such opinions should be excluded.

D. Cytotoxicity

Plaintiffs do not respond to Defendants' argument that Dr. Elliott is not competent to testify about cytotoxicity, and therefore, such opinions should be excluded

E. "Barbed-wire effect"

Plaintiffs do not respond to Defendants' argument that Dr. Elliott is not competent to testify about a "barbed-wire effect," and therefore, such opinions should be excluded

VII. The Court should exclude regulatory and marketing opinions.

Plaintiffs appear to concede that Dr. Elliott will not provide regulatory opinions. Doc 2181, p. 16. Plaintiffs also appear to concede that Dr. Elliott will not provide marketing opinions but claim that his assertion that "I agree with Ethicon's 2012 decision to cease marketing the Prolift System for use in the United States" is not a marketing opinion. Ex. F to Def's Motion, Prolift Report at 3. In doing so, Plaintiffs attempt to equate this statement with a statement that the Court permitted in *Bellew* that "the Prolift System should have never been marketed to surgeons or patients in the first place." Ex. K to Def's Motion, *Bellew* at 18-19.

These two statements are, in fact, very different. The implication of Dr. Elliott's statement that he agrees with the decision to cease marketing Prolift is that Ethicon's marketing decision was premised on an acknowledgment that Prolift is unsafe. This is highly prejudicial. Although Plaintiffs condescendingly assert that "Defendants appear to be unfamiliar with this Court's prior orders" (Doc 2181, p. 20), Plaintiffs ignore that, in *Bellew*, the Court explicitly excluded evidence that Ethicon no longer sells the Prolift product and precluded Dr. Elliott from

testifying about Ethicon's reasoning for withdrawing Prolift. *Bellew v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 165709, at *16 (S.D. W. Va. Nov. 25, 2014); Ex. K to Def's Motion, *Bellew* (11/20/14 Order) at 25.

VIII. The Court should not allow other opinions beyond Dr. Elliott's expertise and/or that are otherwise improper.

Plaintiffs do not object to the remaining challenges to Dr. Elliott's testimony set forth in Section VIII of Defendants' initial brief.

CONCLUSION

For the foregoing reasons and those set forth in Defendants' initial brief, the Court should limit Dr. Elliott's testimony in this case.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, William M. Gage, certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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